

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 52-89 and 108-116, 161-167, 170-176, 179-187, and 196-204 drawn to a G-CSF fusion protein with human albumin, a polynucleotide encoding a G-CSF-albumin fusion protein, a vector comprising it, a host cell harboring the vector, as well as a pharmaceutical formulation containing the fusion protein..

Group II, claims 90-107, drawn to a method of increasing neutrophil levels in a mammal comprising administering the G-CSF albumin fusion protein.

Group III, claims 117-149 and 219, drawn to a G-CSF-immunoglobulin fusion protein.

Group IV , claims 151-160, 168, 169, 177-178, 188-195, and 205-213 drawn to a polynucleotide encoding a G-CSF-Immunoglobulin fusion protein, a vector comprising it, a host cell harboring the vector and a method of producing the protein.

Group V, claims 214-218, drawn to a method of increasing neutrophil levels in a mammal comprising administering the G-CSF immunoglobulin fusion protein.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: glycosylated G-CSF-albumin fusion proteins were known in the art, as evidenced by Yeh et al, U.S. Pat. 5,665,863.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A) Protein sequences as Seq. ID. No.:1 where:

Xaa at position 17 is Cys, Ala, Leu, Ser, or Glu;

Xaa at position 37 is Ala or Asn;

Xaa at position 38 is Thr, or any other amino acid except Pro;

Xaa at position 39 is Tyr, Thr, or Ser;

Xaa at position 57 is Pro or Val; Xaa at position 58 is Trp or Asn;

Xaa at position 59 is Ala or any other amino acid except Pro;

Xaa at position 60 is Pro, Thr, Asn, or Ser,

Xaa at position 61 is Leu, or any other amino acid except Pro;

Xaa at position 62 is Ser or Thr;

Xaa at position 63 is Ser or Asn;

Xaa at position 64 is Cys or any other amino acid except Pro;

Xaa at position 65 is Pro, Ser, or Thr;

Xaa at position 66 is Ser or Thr;

Xaa at position 67 is Gin or Asn;

Xaa at position 68 is Ala or any other amino acid except Pro;

Xaa at position 69 is Leu, Thr, or Ser

Xaa at position 93 is Glu or Asn

Xaa at position 94 is Gly or any other amino acid except Pro;

Xaa at position 95 is Ile, Asn, Ser, or Thr;

Xaa at position 97 is Pro, Ser, Thr, or Asn;

Xaa at position 133 is Thr or Asn;

Xaa at position 134 is Gin or any other amino acid except Pro;

Xaa at position 135 is Gly, Ser, or Thr

Xaa at position 141 is Ala or Asn;

Xaa at position 142 is Ser or any other amino acid except Pro;

and Xaa at position 143 is Ala, Ser, or Thr;

G-CSF [A37N, Y39T]

G-CSF [P57V, W58N, P60T]

G-CSF [P60N, S62T]

G-CSF [S63N, P65T]

G-CSF [Q67N, L69T]

G-CSF [E93N, I95T]

G-CSF [T133N, G135T]

G-CSF [A141N, A143T]

G-CSF [A37N, Y39T, P57V, W58N, P60T]

G-CSF [A37N, Y39T, P60N, S62T]

G-CSF [A37N, Y39T, S63N, P65T]

G-CSF [A37N, Y39T, Q67N, L69T]

G-CSF [A37N, Y39T, E93N, I95T]

G-CSF [A37N, Y39T, T 133N, G 135T]

G, CSF [A37N, Y39T, A141N, A143T]

G-CSF [A37N, Y39T, P57V, W58N, P60T, S63N, P65T]

G-CSF [A37N, Y39T, P57V, W58N, P60T, Q67N, L69T]

G-CSF [A37N, Y39T, S63N, P65T, E93N, I95T].

SEQ ID NO: 22

SEQ ID NO: 33

B) Polynucleotide sequences:

SEQ ID NO: 2

SEQ ID NO: 3

SEQ ID NO: 4

SEQ ID NO: 5

SEQ ID NO: 6

SEQ ID NO: 7

SEQ ID NO: 8

SEQ ID NO: 9

SEQ ID NO: 10

SEQ ID NO: 11

SEQ ID NO: 12

SEQ ID NO: 13

SEQ ID NO: 14

SEQ ID NO: 15

SEQ ID NO: 16 or

SEQ ID NO: 17,

C) Immunoglobulin types:

IgG1, IgG2, IgG3, IgG4, IgE, IgA, IgD, or IgM.

Applicant is required, in reply to this action, to elect **A SINGLE** ultimate species from both the categories A) and B), specify the specific substitutions and the associated Seq. Id. Nos., and, if warranted by the restriction group, a specie from category C), to which the claims shall be restricted, identified by a Seq. Id. No. if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Protein sequences, to claims 52-78, 108-116, 90-107, 117-149, and 214-219.

Polynucleotide sequences, to claims 79-89, 161-169, 170-178, 179-195, and 196-213.

Immunoglobulin types, to claims 137-149.

The following claims are generic: 52, 6184, 117, 126, and 137.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they have different structures.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning this communication or earlier communications from the examiner should be

directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
Primary Examiner, Art Unit 1647